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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,573	03/22/2001	Hector F. DeLuca	1256-00721	9707

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EXAMINER	
JIANG, SHAOJIA A	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/815,573	DELUCA ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's response (remarks/Arguments) filed on June 28, 2004 wherein no amendment is filed, i.e., no claims are amended, cancelled, or newly submitted.

Currently, claims 8-14 are pending in this application. Claims 8-14 are examined on the merits herein.

Applicant's remarks filed June 28, 2004 with respect to the rejection of claims 9-16 made under 35 U.S.C. 112 first paragraph for containing new subject matter which was not described in the original specification and claims, i.e., "a method of reducing the amount of phosphorus in cow manure, comprising replacing a 1α-hydroxylated vitamin D compound for some or all of the inorganic phosphorus in a diet of a dairy cow" and "said feed contains 0% by weight of an inorganic phosphorus supplement" of record stated in the Office Action dated February 24, 2004 have been fully considered and found persuasive to remove the rejection since the specification as originally filed at page 6, lines 12-14 and at page 5, lines 19-22, is seen to provide the support for this limitation. Therefore, the said rejection is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record stated in the Office Action dated February 24, 2004.

The recitation "some" or all in claim 8 is a relative term which renders the instant claims indefinite. The recitation "some" is not defined in the clams and specification. Hence, one of ordinary skill in the art could not interpret the metes and bounds of the patent protection desired as to the recitation "some" of inorganic phosphorus in a diet in the claim. Thus, the claims are indefinite as to how much "some" of inorganic phosphorus in a diet.

Response to Argument

Applicant's arguments filed June 28, 2004 with respect to this rejection made under 35 U.S.C. 112, second paragraph, for indefinite recitation, i.e., "some" have been fully considered but are not deemed persuasive as further discussed below.

Note that Applicant admits that "the term "some" is defined in Webster's New Collegiate Dictionary as being an unspecified or indeterminate quantity, portion, or number as distinguished from the rest of an amount"; and "Although applicant might concede that under other circumstances the term "some" would be indefinite"; however, "applicant does not believe this is so under the circumstances presented by claim 8 herein".

Note that the rejection of the recitation "some" in claim 8 under 35 U.S.C. 112, second paragraph, is because it is a relative term and no definition is given for this

relative term in the clams and specification as pointed out in the previous Office Action. Therefore, one of ordinary skill in the art could not interpret the metes and bounds of the patent protection desired as to the recitation "some" of inorganic phosphorus in a diet in the claim. Thus, the claims are indefinite as to how much "some" of inorganic phosphorus in a diet.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-10 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Deluca et al. (WO 96/24258) for reasons of record stated in the Office Action dated February 24, 2004.

Deluca et al. discloses a method of improving utilization of phosphorus as to reducing or minimizing or eliminating dietary requirements of phosphorus in animals (abstract, page 3 lines 13-15) such as cattle or cow including dairy cow (see particularly page 10 line 10) comprising feeding with the instant 1α-hydroxylated vitamin D compound (see page 7-8 in particular) in the effective amounts within the instant claim (see page 10 line 20-22), may be in a form of top dressing (see page 9 line 3). See also abstract, page 5 line 30 to page 6 line 3, page 9 line 15-17, and claims 18-20.

Thus, the disclosure of Deluca et al. anticipates claims 8-10 and 12-14.

Response to Argument

Applicant's arguments filed June 28, 2004 with respect to this rejection made under 35 U.S.C. 102(b) as being anticipated by Deluca et al. (WO 96/24258) in the previous Office have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art as further discussed below.

Applicant asserts that "the entire disclosure and description set forth in WO 96/24258 is directed toward utilization of phosphorus in phytate complexes, and there is nothing in this reference that teaches or suggests that la-hydroxylated vitamin D compounds could be used to increase utilization of phosphorus from inorganic sources. Contrary to Applicant's assertion, WO 96/24258 particularly discloses that "The vitamin D compounds cause improved utilization of phosphorus, calcium, potassium, magnesium, zinc, iron, and manganese in animal feed as to minimize, or perhaps eliminate the need for supplemental quantities of these minerals in an animal diet" (see abstract). Thus, Deluca et al. (WO 96/24258) discloses the same method for the same intended use and the same object of the present invention.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 102(b). Therefore, said rejection is adhered to.

Claims 1 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by DeLuca et al. (4,338,312) for reasons of record stated in the Office Action dated February 24, 2004.

DeLuca et al. discloses that a 1α-hydroxylated vitamin D such as 1α-hydroxy vitamin D_3, within instant claim, with low phosphorus is useful in a method for

prophylactically treating dairy cattle for parturient paresis. See abstract, col.2 lines 54-65, col.3 Example, and claims 1 and 3. DeLuca's teaching is inherent in a method of maintaining milk production in a dairy cow herein. See *Ex parte Novitski*, 26 USPQ 2d 1389. Thus, DeLuca et al. anticipates the claimed invention.

Response to Argument

Applicant's arguments filed June 28, 2004 with respect to this rejection made under 35 U.S.C. 102(b) as being anticipated by Deluca et al. (4,338,312) in the previous Office have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art as further discussed below.

Applicant argues that "There is no suggestion in the '312 patent of substituting a 1α-hydroxylated vitamin D compound for some or all of the inorganic phosphortls in the cow's diet and then feeding that diet to the cow on a daily basis to maintain milk production at normal levels despite the low P content in the cow's diet" and "The entire disclosure of the '312 patent relates to a method for treating dairy cattle for parturient paresis". Applicant's argument is not found convincing.

Note that DeLuca in the '312 patent discloses clearly and particularly discloses the method for prophylactically treating dairy cow for parturient paresis comprising administering the instant compounds (see claims 1 and 3). Parturient paresis (milk fever) is known to be a metabolic disease of dairy cows including lactating dairy cows resulting from parturition and the initial formation of milk according to DeLuca (col.1 lines 8-15). Moreover, DeLuca teaches low phosphorus in the dairy cow diet (see Example at col.3. Thus, DeLuca's method inherently maintain milk production in a dairy

cow fed a low phosphorus diet, as claimed herein since DeLuca's method steps are same as the instant method steps, administering the same compound in the same amount in a low phosphorus diet to the same dairy cow. See *Ex parte Novitski*, 26 USPQ 2d 1389, 1391 (Bd. Pat. App. & Int. 1993). Further, the instant merely recite "replacing some or all inorganic phosphorus in a diet for a dairy cow....". Thus, DeLuca's method steps are same as herein.

Therefore, DeLuca et al. anticipates claims 1 and 12-13.

Claims 1 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by DeLuca et al. (4,110,446) for reasons of record stated in the Office Action dated February 24, 2004.

DeLuca et al. discloses that a 1α-hydroxylated vitamin D such as 1α,25-dihydroxyvitamin D_3, within instant claim, is useful in a method of treatment and prophylaxis for milk fever in dairy cattle. See abstract, col.2 lines 37-49, col.5 lines 10-19, and claims 1 and 6. DeLuca's teaching is inherent in a method of maintaining milk production in a dairy cow herein by administering . See *Ex parte Novitski*, 26 USPQ 2d 1389. Thus, DeLuca et al. anticipates the claimed invention.

Response to Argument

Applicant's same arguments, filed June 28, 2004 with respect to this rejection made under 35 U.S.C. 102(b) as being anticipated by Deluca et al. (4,110,446), as the 102(b) rejection by DeLuca et al. (4,338,312) have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art, as

discussed above in the 102(b) rejection by DeLuca et al. (4,338,312). In particularly DeLuca et al. teaches that 1α-hydroxylated vitamin D demonstrates a marked ability to prevent the fall in serum calcium and phosphorus levels and effectively maintain blood calcium and phosphorus levels.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 102(b). Therefore, said rejection is adhered to.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLuca et al. (4,338,312 and 4,110,446) for reasons of record stated in the Office Action dated February 24, 2004.

The same disclosure of DeLuca et al. have been discussed above in 102(b) rejections. Note that DeLuca et al. (4,110,446) disclose that the general dosage of the 1α-hydroxylated vitamin D in the range from about 200-400 μg are effective in preventing milk fever of dairy cow (see 4,110,446, col.2 lines 37-39).

DeLuca et al. do not expressly disclose the effective amount of 1α-hydroxylated vitamin D to be administered is 0.1 to 100 μg/kg as a top dressing on the feed. DeLuca

et al. do not expressly disclose that said feed contains 0% by weight of an inorganic phosphorus supplement

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to motivated to optimize the effective amount of 1α-hydroxylated vitamin D to be administered to 0.1 to 100 μg/kg as a top dressing on the feed.

One having ordinary skill in the art at the time the invention was made would have been motivated to optimize the effective amount of 1α-hydroxylated vitamin D to be administered to 0.1 to 100 μg/kg as a top dressing on the feed because the general dosage of the 1α-hydroxylated vitamin D in the range from about 200-400 μg in preventing milk fever of dairy cow is known in the art, and the optimization of the known amounts of known agents to be administered in the form of top dressing on the feed is considered well within the skill of artisan, especially, considered well within conventional skills in food industry.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Applicant's remarks filed on June 28, 2004 with respect to this rejection made under 35 U.S.C. 103(a) of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons. These remarks are believed to be adequately addressed by the obvious rejection presented above.

Additionally, Applicant's results on testing the instant vitamin D compounds in the specification at pages 13-17 have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention but are not deemed persuasive. The results of Tables 2-4 at pages 15-17 showing the effects of the instant vitamin D compounds are clearly expected for the instant claimed method based on the cited prior art. Therefore, the results herein are clearly expected and not unexpected based on the cited prior art. Expected beneficial results are evidence of obviousness. See MPEP § 716.02(c). Results herein provide no clear and convincing evidence of nonobviousness or unexpected results over the cited prior art. Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9307.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Primary Examiner, AU 1617
September 13, 2004